

FEB 24 2006

F-1

F. 510(k) Summary

Submitters information: OMS Medical Supplies, Inc.
230 Libbey Parkway
Weymouth, MA 02189

Contact Person: Mark W. Sheehan
Telephone: 781-340-1072 ext. 20 Fax: 781-340-1637

Date Summary Prepared: April 15, 2005

Device name:	
Proprietary name:	ES-160
Common or usual name:	Portable transcutaneous electrical nerve stimulator (TENS)
Classification name:	Transcutaneous electrical nerve stimulator, Class II, 21 CFR 882.5890.

Legally marketed device for substantial equivalence comparison:
Pointer F-3, K904388

Description of the device:

The device consists of a battery powered portable instrument with a remote grounding pole and a hand held locator/stimulator probe. Six output channels are available for stimulation. The grounding pole is held in order to make contact with the skin. Moving the probe tip across the skin identifies places where the risk of skin burns is low. Auditory signals as well as a meter reading indicate when this has occurred. Holding the probe in place and pushing the stimulation button generates low level electrical pulses as long as the button is pressed.

Intended use of the device:

The ES-160 is intended for use in pain relief. It can be used by a physician on his patients. This is a prescription device and should be used under continued medical supervision. The intended use of the Pointer F-3 is identical. It does not have curative value, but relieves pain symptoms.

The ES-160 cannot be used transcranially, in the carotid sinus area or during pregnancy. Patients suspected of having heart disease should consider adequate precautionary measures prior to administration. Severe spasm of the laryngeal and pharyngeal muscles may occur when an electrode is placed across the neck or mouth. This may be enough to close off the airway. Stimulation will inhibit the output of some demand cardiac pacemakers and therefore, is not recommended for patients with this type of pacemaker.

Electrical nerve stimulation is a symptomatic treatment, and as such may suppress the progress of pain which would otherwise serve as a protective

influence on the outcome of a disease process. The potential for physical and/or psychological dependence upon nerve stimulation as a means of relieving pain has not been determined.

It has been noted that some patients find the sensation of electrical stimulation extremely unpleasant and should probably be excluded from further use of the stimulator.

Technological Characteristics:

Both devices use four 1.5 volt batteries. Both devices have a location mode and a stimulation mode. The location output of both devices is DC current. During stimulation the electrical output for both devices is square waveform pulses. Details of electrical output are different but new safety concerns are not raised by the differences. Controls on each device assess skin burn risk and regulate stimulation intensity. Electrode 510(k) number: K946230.

Performance Data:

Below is the list of the applied standards:

EN 50081-1/1991
EN 50081-3/1993
EN 55011/1998 A1/ 1999
EN 55014-1/ 1993 A2/ 1999
EN 55022/ 1998
EN 60601-1-2/ 1993
EN 61326/ 1997 A1/ 1998
EN 60555-2/ 1987
EN 60555-3/ A1 1992
EN 6100-3-2/A13 1997
EN 61000-3-3/ 1995
IEC 60601-1
IEC 60601-2-10



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2006

Mr. Mark W. Sheehan
OMS Medical Supplies, Inc.
230 Libbey Parkway
Weymouth, Massachusetts 02189

Re: K051020

Trade Name: ES-160 TENS Unit
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZJ
Dated: February 6, 2006
Received: February 8, 2006

Dear Mr. Sheehan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

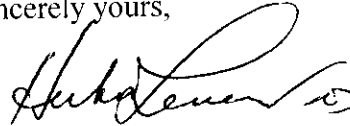
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for

Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Item 2.**Indications for Use**

510(k) Number (if known): K051020, Device Name: ES-160


Indications for Use:

The ES-160 is designed to be used in the treatment of chronic, acute and post-operative pain.

Prescription Use X AND/OR Over-The-Counter Use _____ (Part
21 CFR 810 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number _____